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Hydrogenated Palm Oil

$R^1COOCH_2–CH(OOCR^2)–CH_2OOCR^3$, where R^1, R^2, and R^3 are mainly C_{15} and C_{17};

Hydrogenated palm oil

CAS RN®: 68514-74-9.

DEFINITION

Hydrogenated Palm Oil is the product obtained by refining and hydrogenating the oil obtained from the pulp of the fruit of the oil palm *Elaeis guineensis* Jacq. (Fam. Aracaceae). The product consists mainly of triglycerides of palmitic and stearic acids.

IDENTIFICATION

- **A.** It meets the requirements of the test for *Fats and Fixed Oils, Fatty Acid Composition* ⟨401⟩.
- **B.** It meets the requirements of the test for *Melting Range or Temperature* ⟨741⟩.

IMPURITIES

- **Residue on Ignition** ⟨281⟩

  Sample: 5 g

  Acceptance criteria: NMT 0.1%

- **Limit of Nickel**

  Sample solution: Weigh 5.0 g of Hydrogenated Palm Oil into a previously tared platinum or silica crucible. Cautiously heat the substance, and introduce into it a wick formed from twisted, ashless filter paper. Ignite the wick. When the substance ignites, stop heating. After combustion, ignite in a muffle furnace at about 600°. Continue the incineration until a white ash is obtained. After cooling, with the aid of two 2-mL portions of diluted hydrochloric acid, transfer the residue to a 25-mL volumetric flask, add 0.3 mL of nitric acid, and dilute with water to volume.

  Nickel standard solution: Immediately before use, dilute 10 mL of nickel standard solution TS with water to 500 mL. This solution contains the equivalent of 0.2 µg/mL of nickel.

  Standard solutions: Into four separate identical 10-mL volumetric flasks introduce respectively 0, 1.0, 2.0, and 4.0 mL of *Nickel standard solution*. To each flask add a 2.0-mL portion of the *Sample solution,* and dilute with water to volume to obtain four *Standard solutions* containing added quantities of 0, 0.2, 0.4, and 0.8 µg of nickel, respectively.

  Instrumental conditions

  (See *Atomic Absorption Spectroscopy* ⟨852⟩.)

  Mode: Atomic absorption spectrophotometer equipped with a graphite furnace

  Analytical wavelength: 232.0 nm

  Lamp: Nickel hollow-cathode

  Analysis

  Samples: *Standard solutions*

  Concomitantly determine the absorbances of the *Standard solutions* at least three times each. Record the average of the steady readings for each of the *Standard solutions*. Plot the absorbances of the *Standard solutions* versus the added quantity, in µg, of nickel. Extrapolate the line joining the points on the graph until it meets the quantity axis. The distance between this point and the intersection of the axes represents the quantity of nickel in the 2-mL portion of the *Sample solution* added to the *Standard solutions*.

  Calculate the content of nickel in the portion of Hydrogenated Palm Oil taken:

$$\text{Result} = [V \times (A/V_A)]/W$$

  V = volume of the *Sample solution*, 25 mL

  A = quantity of nickel (µg)

V_A = volume of the *Sample solution* added to the *Standard solutions*, 2 mL

W = weight of Hydrogenated Palm Oil taken to prepare the *Sample solution* (g)

Acceptance criteria: NMT 1 µg/g

- **Alkaline Impurities**

Sample: A mixture of 2.0 g of Hydrogenated Palm Oil, 1.5 mL of alcohol, and 3.0 mL of toluene

Analysis: Dissolve the *Sample* by gentle heating. Add 0.05 mL of bromophenol blue TS, and titrate with 0.01 N hydrochloric acid VS until the mixture turns yellow.

Acceptance criteria: NMT 0.4 mL of 0.01 N hydrochloric acid is required.

SPECIFIC TESTS

- **Melting Range or Temperature ⟨741⟩:** 58°–62°
- **Fats and Fixed Oils,** *Acid Value, Method II* **⟨401⟩:** NMT 2.0
- **Fats and Fixed Oils,** *Fatty Acid Composition* **⟨401⟩:** Hydrogenated Palm Oil exhibits the composition profile of fatty acids as shown in *Table 1*.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage
≤12	0	≤2.5
14	0	0.5–5.9
16	0	32.0–47.0
18	0	49.0–57.0
20	0	≤1.0
22	0	≤1.0
16	1	≤2.5
18	1	≤2.5
18	2	≤0.5
18	3	≤0.5

- **Fats and Fixed Oils,** *Peroxide Value* **⟨401⟩:** NMT 5.0
- **Fats and Fixed Oils,** *Unsaponifiable Matter* **⟨401⟩:** NMT 0.8%
- **Loss on Drying ⟨731⟩**

Analysis: Dry a sample at 105° for 4 h.

Acceptance criteria: NMT 0.1%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers. No storage requirement specified.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
HYDROGENATED PALM OIL	Documentary Standards Support	CE2020 Complex Excipients

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

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